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82. THE U.S. NATIONAL PHARMACEUTICAL STOCKPILE PROGRAM: "BUYING IS THE EASY PART"

Steven D. Bice
Centers for Disease Control and Prevention (CDC)
National Center for Environmental Health
4770 Buford Highway, S.E.
Mail Stop F-23
Atlanta, Georgia 30341, USA

INTRODUCTION

The Centers for Disease Control and Prevention's (CDC) National Pharmaceutical Stockpile (NPS) is a key component of the Nation's plan to mitigate health consequences of biological and/or chemical terrorism. U.S. intelligence authorities project an increased likelihood of an organized bioterrorism assault anywhere in the world. The NPS was initiated in response to a U.S. public policy decision to defend and potentially deter such an attack on U.S. civilians via minimization of resultant death and disease, and to help reduce the burden upon health-care infrastructure and limited assets. The mission of the NPS Program is to help save lives by promptly bringing needed medical materiel to the scene of a bioterrorism event.

The NPS Program is responsible for managing the two major components of the NPS: 12-hour Push Packages and Vendor Managed Inventory (VMI). Program responsibilities include:

- materiel management
- quality assurance/control
- security
- training and education
- technical assistance
- transportation to any designated U.S. location

Since the Program's inception in January 1999, CDC has made significant headway into developing innovative approaches and solutions to difficult challenges associated with the acquisition, storage, stock rotation, transportation, and security of Program assets. With the help of its Federal and commercial partners, CDC successfully tackles obstacles that range from the "easy part," which is the actual purchase of pharmaceuticals and medical supplies, to more difficult hurdles, such as; storage concerns (i.e., physical location, environmental conditions, and security); stock rotation quandaries (e.g., switching out fresh stock for aging stock and the ability to rotate all stock while maintaining adequate inventory levels); transportation dilemmas; and the most challenging component, "timeliness," (i.e., timeliness of transport, timeliness of rotation, and the time between storage site and transport site. To date, CDC has developed a state-of-the-art rotation and storage plan; transportation agreements with U.S.-based major air freight transport firms and the U.S. Department of Defense; and implemented a quality assurance/evaluation model, to assure the quality of materials sent to the field and the quality of mechanisms to get it to the scene of a biological and/or chemical terrorism event.

The primary purpose of this paper is to pose questions concerning issues surrounding the purchase, maintenance, delivery and distribution of a pharmaceutical stockpile for intervention in the event of a catastrophe involving chemical or biologic agents. There are many obstacles to overcome: the CDC, in its efforts to develop the U.S. National

Pharmaceutical Stockpile, has a unique story to tell in the evolution and maintenance of such a stockpile. The CDC story yields many lessons-learned and suggestions. By posing such questions in this paper (and accompanying workshop), the CDC hopes to frame a "checklist" for others (government and industry) who are involved in a similar effort-the establishment of either government or privately owned pharmaceutical stockpiles.

PURCHASING

In order to facilitate the procurement and maintenance of the U.S. National Pharmaceutical Stockpile, it was necessary for CDC to establish an interagency agreement with other U.S. federal agencies, such as the Department of Veterans' Affairs (VA) and the U.S. Department of Defense. CDC, primarily a public health institution, had no mechanisms in place to facilitate the purchase of the thousands of tons of pharmaceuticals and medical supplies needed to establish a national stockpile able to serve the U.S. civilian population. The innovative partnership CDC established with the VA, for example, allowed CDC to take advantage of the VA's existing contract pricing arrangements with its prime vendors of pharmaceuticals, medical/surgical supplies, and other goods and services.

A "procurement powerhouse," the VA routinely purchases over \$2.4 billion dollars of supplies and services annually. This partnership continually saves a vast amount of time, money and resources by allowing CDC to take advantage of existing contract pricing arrangements VA has in place with its prime vendors of pharmaceuticals, medical/surgical supplies, and other goods and services. This partnership allows CDC to purchase pharmaceuticals and medical supplies at costs lower than those CDC would have been able to negotiate had CDC worked alone. Still, there remains a multitude of considerations surrounding the topic of "purchasing." For example, when working with private pharmaceutical manufacturers, one needs to consider what each manufacturer can produce, manufacturer's costs and if there are incentives and/or partnerships that one can tap into (for example, existing partnerships between other government agencies and private organizations).

The entire questions related to the subjects of "what to buy?" and "how much?" require careful consideration and methodical "behind the scenes" effort in order to determine the answers. The answers are tied into estimating the requirements, the numbers of potentially exposed and the numbers requiring treatment. In addition, special populations must be considered-- to include children, immune compromised patients, frail elderly and institutionalized persons, migrant populations, etc.

Currently, a single 12-hour Push Package within CDC's stockpile has the capacity to provide post-exposure prophylaxis to many thousands of persons. The number varies with such factors as the threat agent, the condition of patients who need specific care, the antibiotic, or antibiotics, to be used, the proportional dose(s) of antibiotic(s) that will be dispensed, and the treatment time interval. NPS antibiotic proportions are based on assumptions about the most likely weaponized biological threat agents, taken from expert advice and available literature on the subject. CDC's purchasing decisions were made assuming the largest proportion of persons exposed to any biological threat agent would require oral medication for post-exposure prophylaxis. In addition, CDC calls for follow-on inventory to supplement a 12-hour Push Package with specified medical materiel in several orders of magnitude greater than the all eight NPS initial response packages.

OVERSIGHT AND MAINTENANCE

There are many questions associated with the oversight and maintenance of a pharmaceutical stockpile. The challenges associated with storage, quality assurance, quality

control, inspections, and inventory management are boundless—encompassed by the overall questions, “Who is responsible?” and “Who does what and when?” Under these are many layers of complex questions, for example, when product reaches its shelf-life end-date, “What do you do with it?”

The systems CDC uses to manage the inventory in the NPS were developed through months of trial and error and intense “brain storming” sessions. The inventory management system, for example, is very detailed. It captures: item description, unit of measure, total Push Package amounts, individual Push Package amounts, quantity-on-hand, quantity-on-order, difference between on-hand and on-order, rotation months left on item, estimated cost/unit, overhead costs, current push package expenditures, total push package cost, individual push package cost, source, ID number, cubic feet/unit, cubic feet/total push packages, cubic feet/individual push package, unit weight, weight of total push packages, weight of individual push package, and readiness status. The process of developing and managing such a system is laden with difficulties that can only be overcome with a systematic process.

To address stock rotation issues, the CDC’s NPS Program adopted a unique, state-of-the-art rotation and storage system that will ensure that NPS assets remain “fresh” without using the traditional “buy and dispose” rotation methods used in the management of other pharmaceutical stockpiles. Through this system, CDC will be able to exchange most of the nearly expired pharmaceuticals within the push packages for “fresh” inventory. The NPS Program’s storage and rotation contractor will then sell the nearly expired inventory to their customer base—to those customers who have immediate need. This system solves the problematic issues associated with a fixed budget and a need to keep fresh inventory. The system is expected to save millions of dollars.

CDC relied on extensive transportation and logistical research performed by major worldwide transportation carriers, the U.S. Department of Defense and consultants to determine permanent Push Package storage sites. Sites were chosen to enhance and provide maximal response timeliness and coverage. Comparative elements of this research included: air hub aircraft availability, traffic volume, air courier staff availability, population densities, regional weather characteristics, and U.S. Department of Defense assets and their availability, etc. Because of this research, CDC’s NPS Program teamed with the public, federal and private airfreight carriers so that timeliness is ensured.

LOGISTICAL CONSIDERATIONS, TRANSPORT AND DELIVERY

“How is a stockpile delivered?” “What will it look like when its delivered?”, “Who knows what products are located where?”, “Why are things packaged the way they are?”, “What is the loading plan?”, “What are the timeframes for delivery?”, and “How should we unload the cargo once it arrives?”

The logistical issues associated with the delivery of a stockpile are numerous and confounding. The decisions that the CDC made concerning its stockpile were made after months of inventive logistical thinking and solicitation of expert advice. CDC remains open to exploring better and more efficient methods for transport and delivery—to ensure life-saving redundancies are built into the Program. To date, the NPS Program is organized around a two-tiered response: 12-hour Push Packages and Vendor Managed Inventory. The 12-hour Push Packages consist of identical assemblages of medical materiel. They are pre-positioned at strategic locations nationwide, which facilitate transport by air or ground. They can reach any city in the continental United States, Alaska, Hawaii, and most United States Territories within 12 hours of the notification to deploy.

CDC established tentative agreements with the U.S. Department of Defense and private air cargo transporters to meet the transport needs of the NPS Program. CDC chose

these partners and the U.S. Department of Defense to build in redundancies in air transport capability: when one option fails, another is available. CDC also chose to go with more than one partner to reduce or eliminate shortcomings with any one partners' capabilities. In addition, all partners have agreements in place with several subsidiary companies--agreements that give the transporters access to several hundred additional cargo aircraft. Finally, all partners offer CDC a wide assortment of ground transportation capabilities that can move the 12-hour Push Packages on those occasions when air cargo is infeasible or impractical. All of this puts CDC's ultimate goal within reach—which is to reduce the time it takes to prepare and transport any or all of the 12-hour Push Packages to the scene of a biological and/or chemical terrorism event.

As the first response, a 12-hour Push Package may be deployed amidst uncertainty about what threat agent has been used, and whether more than one has been released. The NPS cannot be an affected area's first response to a chemical and/or biological terrorism event; however, a 12-hour Push Package can thereafter serve as the potential lifeline in responding to any of several biological, chemical or conventional weapons.

To meet this broad challenge, a single 12-hour Push Package contains more than 90 product categories which include adult and pediatric oral drug preparations; intravenous drug preparations; chemical antidote preparations; different emergency medications; several thousand cases of various sized IV catheters and administration sets; items to help establish and maintain patient airways; fluid for re-hydration; bandaging, and trauma supplies. This all translates into important facts about the size and scope of the NPS that have planning implications. These facts are that:

- One 12-hour Push Package will arrive in over 100 specially designed cargo containers.
- These containers transport more than 10,000 cubic feet of materiel.
- One 12-hour Push Package weighs 100,000 pounds (50 tons), filling a wide body cargo aircraft, such as a Boeing 747 or 767.
- One 12-hour Push Package carried by ground will fill four 48-foot semi tractor-trailers.

DISTRIBUTION

When the NPS Program evaluated available options for manufacturer packaging of oral antibiotics, consideration was given to the questions, "Why not unit or single patient dosing instead of bulk product?" and "How will bulk product be broken down in a crisis situation?"

The CDC put much thought into these questions and in the "unit-dose" system, commonly used in the hospital setting. These individually wrapped tablets (i.e., "blister packs") provide immediate dispensing capability without the need to repackage. Each NPS 12-hour Push Package does contain a quantity of "blister packs" of the oral drugs for selected biological agents—in order to meet the immediate needs for post-exposure prophylaxis of the first responder community and their immediate family members, or as a means to get an immediate dose to persons in the affected area. However, most of the NPS comes in bulk packaging rather than in unit doses. CDC found that putting the entire NPS into unit doses was cost (and coverage) prohibitive. The cost of procuring that type of packaging was higher than the bulk bottle form, and that would limit the extent and speed with which the NPS Program initially could prepare for bioterrorism events involving thousands to millions of persons. Second, as this packaging form is limited to hospital (non-retail) settings, it provides limited stock rotation capability, forcing CDC into the costly option of destroying/ replacing expired stock. That would limit CDC's ability (in future years) to expand the number of

persons able to receive post-exposure prophylaxis in a bioterrorism event. Finally, consideration was given to purchasing bulk form and repackaging in advance, before any request for NPS activation. FDA regulation requires repackaged bulk tablets be given an expiration date 6 months from the date of repackaging. This greatly cuts the average product shelf-life of 2 years. CDC viewed these disadvantages and decided to keep tablets in their manufacturer bulk bottles.

This brings us to more questions. "How are points of distribution established?" "What are the criteria used to establish of point of distribution?" "What do health care providers need to know and how can private corporations help?", "What do you tell the victims?" , and "How do you inform or educate the patients to ensure or enhance compliance in taking medications and overall understanding?" Many of these questions are still undergoing development at CDC. CDC's first priority was to purchase and "stockpile" the materiel – that accomplished, we are working on addressing these questions that will prompt further planning crucial to the successful distribution of NPS materiel in the event of a crisis.

KEY WORDS

Pharmaceuticals, medical supplies, stockpile, emergency response, repository, national asset